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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/905,755 07/13/2001 Jing Cheng 265/247 4001 10/05/2004 EXAMINER 34263 7590 O'MELVENY & MEYERS BARTON, JEFFREY THOMAS 114 PACIFICA, SUITE 100 IRVINE, CA 92618 ART UNIT PAPER NUMBER

1753

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		<i>/</i> ,
Office Action Summary	Application No.	Applicant(s)
	09/905,755	CHENG ET AL.
	Examiner	Art Unit
	Jeffrey T. Barton	1753
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with t	he correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply ly within the statutory minimum of thirty (30 will apply and will expire SIX (6) MONTHS e. cause the application to become ABANC	be timely filed) days will be considered timely. from the mailing date of this communication. ONED (35 U.S.C. & 133)
Status		
	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims	en parto quayro, 1000 o.b. Th	,, 400 0.0. 210.
4) Claim(s) 1-20 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o Application Papers 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accompanion and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct	wn from consideration. or election requirement. er. epted or b) objected to by the drawing(s) be held in abeyance. tion is required if the drawing(s) is	See 37 CFR 1.85(a). s objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Ex	carmiler. Note the attached Of	lice Action of form PTO-152.
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Appli rity documents have been rec u (PCT Rule 17.2(a)).	cation No eived in this National Stage
Attachment(s) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 20010713, 20030929.	4) Interview Sumn Paper No(s)/Ma 5) Notice of Inform 6) Other: <u>IDS 2004</u>	il Date nal Patent Application (PTO-152)

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DETAILED ACTION

Priority

1. The status of this application as a continuation of both 09/548,522 (Filed 13 April 2000) and 09/016,596 (Filed 30 January 1998), now U.S. Patents No. 6,280,590 and 6,071,394, respectively is acknowledged. The status of this application as a continuation-in-part of 08/709,358 (Filed 6 September 1996), now U.S. Patent No. 6,129,828 is acknowledged, but insufficient support was found therein for a microfabricated chip-type device with electrode arrays, permeation layers on the electrodes, or a u-shape. Therefore benefit of this earlier filing date is not granted for these aspects of the claimed invention.

Specification

2. The disclosure is objected to because of the following informalities: Application 09/548,522 has been issued as Patent 6,280,590. In the Related Applications Statement section, please replace "U.S. Application No. 09/548,522, filed on April 13, 2000," with "U.S. Application No. 09/548,522, filed on April 13, 2000, now U.S. Patent No. 6,280,590,"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The independent claims 1 and 13 include the limitation that the claimed system comprise "a channel-less flow chamber having a partition". The nature of this partition is not described in the specification - is it a physical barrier of some sort, or simply a spacing between arrays? Can it be either? If it is a physical barrier, must it extend across the entire width of the chamber, and must it be permeable to the analytes?

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Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 8. Claims 1, 2, 4-9, 13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (WO 96/07917) in view of Markx et al. (*J. Biotechnol.* 1996)

Relevant to claims 1 and 13, Heller et al disclose an assay system, comprising a reaction apparatus (Figure 6) comprising: a microfabricated chip (Page 8, lines 4-5) having a plurality of electrodes (e.g. cell sorter matrix 66; Page 18, line 23 - Page 19, line 5; general matrix discussion on pages 13-17), each electrode being coated with a permeation layer (Page 18, lines 26-29), and the chip being mounted on a printed circuit board (Figure 3, or Page 26, lines 9-13); a "channel-less" flow chamber (Figure 9 shows cover 136 defining a chamber; Page 28, lines 19-22) having a partition to define two reaction areas within the chamber (cell sorter matrix and APEX chip, separated on the chip by partitions (DNA and Fragment selectors)), wherein the flow chamber is mounted over the chip (Figure 9); an output connector for electrically coupling the reaction

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apparatus to a controller (Figure 7); a controller electrically coupled to the apparatus. (Figure 7); and a laser subsystem configured to deliver excitation energy to the electrodes. (Page 25, lines 10-15)

They also disclose a fluid inlet port to the flow chamber. (Figure 6; Page 18, lines 17-22)

Relevant to claim 2, Heller et al disclose a flow chamber comprising a detection window. (Figure 9, port 138; also Page 38, lines 12-13)

Relevant to claim 4, Heller et al disclose the plurality of electrodes comprising two arrays of electrodes, each corresponding to a separate reaction area. (Figure 6, Cell sorter matrix and APEX chip)

Relevant to claim 5, Heller et al disclose the electrodes being disposed in a checkerboard format, with each electrode being individually addressable, and thus capable of checkerboard bias (i.e. alternating polarity for neighboring electrodes). (Figure 3; Page 22, line 29 - Page 24, line 36)

Relevant to claim 6, Heller et al disclose the ability to individually address electrodes with a signal of any polarity. This would allow a square array to be divided into an array of electrodes and a sub-array of counterelectrodes depending on polarities provided at the operator's choosing, with one type in the majority able to be termed "electrode" as stated in this claim. An example is given on Page 23, lines 8-12.

Relevant to claim 7, Heller et al disclose capture probes immobilized on the permeation layer. (Page 20, lines 14-31)

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Relevant to claims 8 and 16, Heller et al disclose no particular volume for the flow chamber, but disclose microscale fabrication techniques (Page 8, lines 4-12) that would be capable of producing devices with a volume as low as 10 microliters.

Relevant to claim 15, Heller et al disclose the system comprising a cooled charge-coupled device capable of detecting signals from the electrodes after delivery of the excitation energy to the electrodes. (Page 25, lines 27-29)

Heller et al do not explicitly disclose their system comprising a plurality of tubes leading to the flow chamber, or a pump coupled to the tubes. (Claims 1 and 13) They also do not disclose a fluid reservoir coupled to the pump. (Claim 9)

Markx et al disclose a dielectrophoretic separation apparatus in which fluid is introduced to the device, and exits the device through a plurality (i.e. 2) of tubes. Flow is generated by a pump coupled to a fluid reservoir. (Figure 1)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Heller et al by causing fluid ingress and egress to and from the chamber using tubing and a pump coupled to a reservoir, as taught by Markx et al, because it would provide a convenient, controllable, and reproducible means of causing fluid flow.

Relevant to claims 8 and 16, recitation of a particular size (in this case, volume) without further distinction from prior art does not provide patentability. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the

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claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (WO 96/07917) and Markx et al (*J. Biotechnol.* 1996) as applied to Claim 1 above, and further in view of Betts et al.

Heller et al and Markx et al disclose a combined system as described above in addressing claim 1. In addition, Heller et al disclose using a waveform generator coupled to the electrodes to generate electrode signals. (Page 22, line 19 - Page 24, line 36)

Neither Heller et al nor Markx et al explicitly disclose the use of an oscillator to monitor signals from the electrodes.

Betts et al disclose a dielectrophoretic device in which they use an oscilloscope to monitor signals from the electrodes. (Column 5, lines 1-6)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Heller et al and Markx et al by adding an oscilloscope to monitor signals from the electrodes, as taught by Betts et al, because it would provide accurate data on the frequency and amplitude of the electrical signal at the electrodes.

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10. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (WO 96/07917) and Markx et al (*J. Biotechnol.* 1996) as applied to claim 1 above, and further in view of Laas et al.

Heller et al and Markx et al disclose a combined system as described above in addressing claim 1. Additionally, Heller et al disclose the plurality of electrodes comprising two arrays of electrodes, each corresponding to a separate reaction area. (Figure 6, Cell sorter matrix and APEX chip)

Regarding claim 12, Heller et al also disclose a larger matrix area for the cell sorter than for the analytical device (i.e. APEX) (Page 18, lines 30-32)

Neither Heller et al nor Markx et al explicitly disclose the system comprising a U-shaped flow chamber (Claim 10), or a third tube, where two tubes are coupled to the firs reaction area, and the third to the second reaction area (Claim 11).

Laas et al disclose an electrophoretic device with a U-shaped channel. (Figure 1)

It would have been obvious to one having ordinary skill in the art to modify the combination of Heller et al and Markx et al by providing a U-shaped flow chamber, because the wording of the independent claim (i.e. the flow chamber having a partition) can define a U-shaped chamber, if flow between the two chambers is needed, and a single-section partition is desired. Additionally, such geometries have been used before in electrophoresis. (See Laas et al, Figure 1)

Regarding claim 11, it would also have been obvious to provide at least three tubes to provide flow from other device components (Figure 6; e.g. reagent dispenser system or waste disposal system), and from the APEX system downstream to the

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fragment storage system, because it would provide a contained, convenient passage for fluid flow.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (WO 96/07917) and Markx et al (*J. Biotechnol.* 1996) as applied to Claim 1 above, and further in view of Kambara et al.

Heller et al and Markx et al disclose a combined system as described above in addressing claim 1. In addition, Heller et al disclose using an optic fiber coupled to the laser component, capable of delivering excitation energy to the electrodes (Page 25, lines 16-20; Figure 9, optical path 128 adjacent electrode 120), as well as using fluorescence for detection of analytes. (Page 25, lines 10-15)

Neither Heller et al nor Markx et al explicitly disclose the use of a He-Ne laser in their systems.

Kambara et al disclose an electrophoresis system in which they use a He-Ne laser to excite fluorescent moieties for subsequent detection. (Column 11, lines 15-21)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Heller et al and Markx et al by using a He-Ne laser as the excitation light source, as taught by Kambara et al, because Heller et al do not specify a preferred laser for this purpose, and Kambara et al teach its usefulness in detecting labeled analytes.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 2, 4-7, 9-13, and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-7 of U.S. Patent No. 6,280,590 in view of Heller et al (WO 96/07917) and Markx et al. (*J. Biotechnol.* 1996)

Relevant to claims 1 and 13, claim 7 of U.S. Patent No. 6,280,590 claims a system with all limitations of the instant claims, except that it does not require the chip to be mounted on a printed circuit board, and it does not require the controller, output connector or pump. Specific to claim 13, claim 7 of U.S. Patent No. 6,280,590 does not explicitly disclose a laser subsystem.

Relevant to claim 4, claim 7 of U.S. Patent No. 6,280,590 corresponds to these limitations.

Instant claims 5, 6, and 7 correspond to claims 6, 3, and 4 of U.S. Patent No. 6,280,590.

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Relevant to claim 10, claim 7 of U.S. Patent No. 6,280,590, claims a partition between the first and second area of the chamber. If the chamber is to allow flow between the two areas, there must be an opening (i.e. partition does not run the entire length of the chamber), which would result in a U-shaped chamber.

Relevant to claim 12, claim 3 of U.S. Patent No. 6,280,590 claims at least a pair of counter electrodes, which would comprise an array with fewer electrodes that in the first array.

Claims 3-7 of U.S. Patent No. 6,280,590 do not explicitly disclose the chip being mounted on a printed circuit board, or a system comprising a controller, output connector or pump. (Claims 1 and 13) They also do not disclose a detection window in the flow chamber (Claim 2), a reservoir coupled to the pump (Claim 9), a system comprising a laser subsystem (Claim 13), or a cooled color charge-coupled device. (Claim 15)

Heller et al disclose their flow chamber being mounted on a printed circuit board (Figure 3, or Page 26, lines 9-13), an output connector for coupling the apparatus to a controller, and the controller itself. (Figure 7) They also disclose a laser subsystem within their system (Page 25, lines 10-15) and a cooled charge-coupled device for detecting signals from the electrodes after delivery of the excitation energy to the electrodes. (Page 25, lines 27-29)

Markx et al disclose a pump coupled to a plurality of tubes in fluid communication with a dielectrophoretic device. (Figure 1) They also disclose a reservoir coupled to the pump. (Figure 1)

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Relevant to claims 1 and 13, it would have been obvious to one having ordinary skill in the art to modify the system claimed in Claims 3-7 of U.S. Patent No. 6,290,590 by disposing the chip on a printed circuit board, as taught by Heller et al, because it would provide facile connection of a voltage source to the numerous electrodes of the device.

Relevant to claims 1 and 13, it would also have been obvious to provide an output connector and controller to the apparatus, as also taught by Heller et al, because they are necessary for device operation.

Relevant to claims 1, 9, and 13, it would also have been obvious to provide a pump coupled to a reservoir and to the tubes of the device, as taught by Markx et al, because it would provide a convenient, controllable, and reproducible means of causing fluid flow.

Relevant to claim 11, it would have also been obvious to provide a third tube to either of the chambers, because it would allow a user to address one area of the chamber without disturbing the other area by closing or opening a single tube.

Relevant to claim 13, it would have also been obvious to provide a laser subsystem to the device, as taught by Heller et al, because it would provide an accurate means of providing excitation energy necessary for fluorescence detection.

Relevant to claim 15, it would also have been obvious to provide a detector comprising a cooled charge-coupled device for detecting the fluorescence signal, because it would provide an accurate means of measuring the fluorescence intensity.

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14. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-7 of U.S. Patent No. 6,280,590, Heller et al (WO 96/07917), and Markx et al. (*J. Biotechnol.* 1996) as applied to claim 1 above, and further in view of Betts et al. The material disclosed by the various references and the motivation for their combination are as described above in paragraph 9.

15. Claims 8 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-7 of U.S. Patent No. 6,280,590, Heller et al (WO 96/07917), and Markx et al. (*J. Biotechnol.* 1996) as applied to claims 1 and 13 above, and further in view of claim 6 of U.S. Patent No. 6,071,394.

Claims 3-7 of U.S. Patent No. 6,280,590, Heller et al, and Markx et al disclose a combination as described above.

None among claims 3-7 of U.S. Patent No. 6,280,590, Heller et al, and Markx et al explicitly disclose a device having a volume of about 10 microliters.

Claim 6 of U.S. Patent No. 6,071,394 discloses a directly related device with a volume of 10 microliters.

It would have been obvious to one having ordinary skill in the art to modify the combination of claims 3-7 of U.S. Patent No. 6,280,590, Heller et al, and Markx et al by providing a device with a volume of 10 microliters, because a directly related device with this volume was claimed in a related application.

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16. Claim 14 is rejected under the judicially created doctrine of obviousness-type

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Heller et al (WO 96/07917), and Markx et al. (J. Biotechnol. 1996) as applied to claim 1

double patenting as being unpatentable over claims 3-7 of U.S. Patent No. 6,280,590,

above, and further in view of Kambara et al. The material disclosed by the various

references and the motivation for their combination are as described above in

paragraph 11.

17. Claims 17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,280,590 in view of Heller et al (WO 96/07917), Markx et al (*J. Biotechnol.* 1996) and Heller et al (U.S. 5,605,662).

Claim 8 of U.S. Patent No. 6,280,590 claims a method according to all limitations of instant claim 17, except that it does not require the device to include a chip or a laser subsystem, and the method does not include steps of washing, staining, or image generation. Furthermore, pumping for introduction of fluids is not required.

Relevant to claim 20, claim 8 of U.S. Patent No. 6,280,590 discloses the materials being lysed by subjection of the materials to pulses having alternate polarity. The biasing in checkerboard format can be construed as dividing the array into two distinct electrode arrays.

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Claim 8 of U.S. Patent No. 6,280,590 does not disclose a method using a device having a chip or a laser subsystem, and the method does not disclose steps of pumping, washing, staining, or image generation.

Heller et al (WO 96/07917) discloses a device disposed on a chip (Figure 3), including a laser subsystem to deliver excitation energy. (Page 25, lines 10-15) The detection step of Heller's method for using this device involved image formation from the fluorescence caused by the excitation energy delivered by the laser. (Page 25, lines 27-29)

Markx et al disclose using a pump to introduce fluids to a dielectrophoretic device. (Figure 1)

Heller et al (U.S. 5,605,662) disclose a related electrode array-based biological reaction/analysis device, and methods for its use, comprising steps of washing undesired materials away and staining the desired materials (Column 26, lines 41-47)

Relevant to claim 18, Heller et al (U.S. 5,605,662) disclose the current to the electrode array being maintained during washing. (Column 26, lines 41-47)

Relevant to claim 19, Heller et al (U.S. 5,605,662) disclose the staining step being accomplished with a fluorescent dye. (Column 26, lines 41-47)

It would have been obvious to one having ordinary skill in the art to modify the method of Claim 8 of U.S. Patent No. 6,280,590 by performing it within a chip-based device having a laser subsystem, as taught by Heller et al (WO 96/07917) because it would facilitate utilization of numerous electrodes within the method, and provide an accurate means of providing excitation energy necessary for fluorescence detection.

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It would also have been obvious to further modify the method to include steps of washing away undesired materials and staining the desired materials, as taught by Heller et al (U.S. 5,605,662), because it would increase accuracy of analyses.

It would also have been obvious to further modify the method by generating an image of the desired materials through laser fluorescence detection, as taught by Heller et al (WO 96/07917), because it would give more easily understood output than raw data.

It would also have been obvious to further modify the method by performing the washing step while current is still applied to the electrodes, as taught by Heller et al (U.S. 5,605,662), because it would minimize sample loss.

It would also have been obvious to further modify the method by staining with a fluorescent dye, as taught by Heller et al (U.S. 5,605,662), because it provides a relatively strong signal for dilute samples.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB October 1, 2004

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